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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,123	12/03/2001	Paul David James Blackler	P32292	2730

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,123

Applicant(s)

BLACKLER ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-23, 27 and 32-34 is/are rejected.
- 7) ☒ Claim(s) 24-26 and 28-31 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other: .

Detailed Action

All of the rejections at paper no. 9 are withdrawn in light of applicant's canceling of claims 1-10 and 14 at paper no. 10B.

(new rejections and objections)

Applicant is advised that should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 23 be found allowable, claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-24, 27, 32, 33, 34 are rejected under 35 U. S. C. 103(a) as being unpatentable over Patel (See Reference N). Patel. al. teaches the instant compound, 5-[4[2-(N-,ethyl-N-2-pyridyl)amino)ethoxy]Benzyl]Thiazolidine-2, 4-dione. At pages 1-13, see the instant compound

The difference between the prior art compound and the instantly claimed compound is that the claimed compound is a polymorph of the Patel compound. A polymorph is a solid crystalline phase of a given compound resulting from the possibility of at least two different arrangements of the molecules of that compound in the solid state. The instant compound discloses the infrared spectrum, Raman spectrum, NMR, and X-ray diffraction pattern for 5-[4[2-(N-,ethyl-N-2-pyridyl)amino)ethoxy]Benzyl]Thiazolidine-2, 4-dione. The Patel reference does not disclose such data for 5-[4[2-(N-,ethyl-N-2-pyridyl)amino)ethoxy]Benzyl]Thiazolidine-2, 4-dione.

It would have been obvious to one of ordinary skill in the art to create a polymorph of the infra red spectrum, Raman spectrum, NMR, and X-ray diffraction pattern for 5-[4[2-(N-,ethyl-N-2-pyridyl)amino)ethoxy]Benzyl]Thiazolidine-2, 4-dione that does not show unexpected properties from the known compound. Accordingly, the compounds are deemed unpatentable there from in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim(s) 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 16 recites the limitation "Figure I" in line 2, page 2 of the amendment 10B.

There is insufficient antecedent basis for this limitation in the claim.

B. Claim 17 recites the limitation "Figure II" in line 2, page 2 of the amendment 10B.

There is insufficient antecedent basis for this limitation in the claim.

C. Claim 18 recites the limitation "Figure III" in line 2, page 2 of the amendment

10B. There is insufficient antecedent basis for this limitation in the claim.

D. Claim 19 recites the limitation "Table I" in line 2, page 2 of the amendment 10B.

There is insufficient antecedent basis for this limitation in the claim.

E. Claim 20 recites the limitation "Figure IV" in line 2, page 2 of the amendment

10B. There is insufficient antecedent basis for this limitation in the claim.

F. Claim 21 recites the limitation "Table II" in line 2, page 2 of the amendment 10B.

There is insufficient antecedent basis for this limitation in the claim.

G. In claim 22, line 1, page 2, the term "isolated" is indefinite. How isolated is the polymorph?

H. In claim 23, line 1, page 2, the term "pure" is indefinite. How pure is the polymorph?

Claims 24, 25, 26, 28, 29, 30-31 are objected to because they are based on a rejected claim.

The IDS filed 3/21/03 has been considered.

Response To Applicant's Remarks

103 (a) rejection

The applicant traverses the 103 (a) rejection asserting that the Patel reference fails to support a prime facie case of obviousness, and fails to provide any basis for an expectation of success. However, it is the applicant's job to show that the instant compound has unexpected results as a polymorphic form over the nonpolymorphic form. The applicant has not shown unexpected results over the Patel compound.

112, second paragraph rejection

Applicants traversed the rejection of claims 2-5 under 35 U. S. C. 112, and have included new claims 16-21 with reference to a figure or Table, asserting that these claims are written in accordance with M. P. E. P 2173.05 (s). However, M. P. E. P. 2173 (s) says that claims may only incorporate a specific figure or table" in exceptional circumstances. The applicant has not depicted in the claims what Figures I-IV" and Tables I and II are in the actual claims. References to these figures in the specification is not sufficient.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Binta Robinson

June 2, 2003